A Multicenter Randomized, Double-Blinded, Placebo-Controlled Study of Posaconazole in Genetically-Defined Patients With Active Crohn's Disease

NCT04966585

November 22, 2022

CEDARS-SINAI MEDICAL CENTER

# EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Subject Initial: _____ Date: _____

CEDARS-SINAI MEDICAL CENTER

# CONSENT FORM FOR RESEARCH

**Title:** A MULTICENTER RANDOMIZED, DOUBLE-BLINDED, PLACEBO-CONTROLLED STUDY OF POSACONAZOLE IN GENETICALLY-DEFINED PATIENTS WITH ACTIVE CROHN'S DISEASE

**STUDY SUPPORT PROVIDED BY: NATIONAL INSTITUTE OF HEALTH**

**PRINCIPAL INVESTIGATOR:**
**GIL MELMED, MD**

**STUDY CONTACT PHONE NUMBER AT CSMC: 310-423-4100**

**AFTER HOURS CONTACT (24 HOURS): 310-423-4100**

This research study is sponsored by the National Institute of Health (NIH). The NIH only reimburses Cedars-Sinai Medical Center for the costs associated with running the study; NIH is not providing additional compensation to Cedars Sinai Medical Center or the Principal Investigator for their participation in the study.

## KEY INFORMATION ABOUT THIS RESEARCH STUDY

We are seeking your consent to take part in this research study. Your participation in this research is voluntary. If you choose to participate, you can stop at any time. Please consider the following summary, along with the more detailed information provided throughout this consent form.

- The purpose of this study is to evaluate the effects of oral posaconazole (Noxafil®, Merck) for the treatment of active Crohn's disease.
- The main procedures of this study include physical exams, laboratory tests, colonoscopy with biopsies, EKGs, chest x-rays, completion of questionnaires, and a daily diary. If you choose to take part in this study, your participation will last about 40 weeks.
- All research studies involve some risks. Risks or discomforts from this study may include diarrhea, pyrexia (fever), and nausea.
- You are not expected to benefit from taking part in this research study, but the information learned from this study may help others in the future.
- If you choose not to participate, there may be other choices available to you. Some other choices may include following the usual clinical approach (commonly-used Crohn's

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disease therapy, surgery, or participation in other studies). You will not lose any services, benefits or rights you would normally have if you choose not to participate. Please discuss your choices with the researchers.

Please take time to read this entire form and ask questions before deciding whether to participate in this study. You are encouraged to talk with family members, friends, and/or healthcare providers before you make your decision.

## 1. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

We are doing this study to examine the effects of oral posaconazole (Noxafil®, Merck) for the treatment of active Crohn's disease.

You are being asked to take part in this research study because you were diagnosed with Crohn's disease and are at risk for fungal infection based on genetic determination. Data suggests that fungi play an important role in the development of Crohn's disease and that some individuals may be genetically predisposed to specific fungi responsive to posaconazole.

The study will enroll up to 24 people in total at 2 sites.

This research study is designed to test the investigational use of posaconazole (Noxafil®, Merck). This drug is approved by the U.S. Food and Drug Administration (FDA) for the treatment of fungal infections. However, it is not approved by the FDA for Crohn's disease.

## 2. WHAT WILL HAPPEN DURING THE STUDY?

This section provides a general overview of what will happen during your participation in this study. Information included below should be considered along with the flowchart of procedures attached as an Appendix.

The flowchart shows a timeline for research-related or standard of care procedures that are involved in your participation in this study. **Research-related procedures** are those performed solely for the research. They would not be performed if you did not take part in the study. **Standard of care (routine)** procedures would be performed both as part of this study and if you do not participate in this study.

A table describing common medical procedures done solely for the purposes of monitoring and assessing your condition during this study is attached as an Appendix to the end of this consent form. Standard of care procedures that will be repeated or done at greater frequency are listed in the flow chart Appendix.

Overview of Study:

This is a randomized, double-blinded, placebo-controlled clinical trial.

Randomized means that you will be assigned to a study group by chance, like a flip of a coin. You will be randomized into one of two groups, a treatment group, or the placebo group. You will have an equal chance of being placed in one of the groups described above. This is also a

Double-blind study; this means neither you nor the researchers will know what group you are assigned to.

Once you have completed the screening period and are found to be eligible you will begin the treatment period. If you are randomized to the treatment group, you will receive the following:

Dosing of posaconazole (Noxafil®, Merck), or matching placebo, will begin at the Baseline visit

- Loading Dose: 300 mg twice a day at baseline
- Maintenance Dose: 300 mg once a day for 12 weeks

After completing the treatment period, at the Week 12 visit you will begin a 6-month follow-up period. If you had received placebo and had no response you will begin a 12-week open label dosing period followed by a 12-week follow-up period.

Capsules (or tablets for the open-label portion of the study) should be taken with food, you should swallow the capsules or tablets whole, do not divide, crush or chew them. Please keep your capsule or tablet containers and bring them with you to all the follow-up visits.

In order to properly follow the study's protocol (research plan), all participants will receive treatments and procedures that have been pre-determined by the protocol. In effect, the protocol describes which medications or procedures you will receive, rather than those decisions being made by your personal doctor or based on your preference. There may be options available outside of this study that you will not be able to receive while participating in this study. We do not believe you should be at any increased risk due to this limitation.

Biomarkers

A biomarker is a biological molecule found in blood, other body fluids, or tissues that may be a sign of a condition or disease. Biomarkers are good indicators of treatment response. Serum and stool samples will be obtained throughout the study for biomarker testing.

How long will you be in the study?

We think you will be in this study for/until about 40 weeks. The total time includes a 4-week screening period, 12 weeks of posaconazole therapy, 12 weeks open-label for eligible subjects, and a follow-up period of 12 weeks or a follow-up of 24 week for subjects not in open-label.

## 3. WHAT ARE THE POSSIBLE RISKS?

Risks of common medical procedures performed solely for research purposes are described in a table attached to the end of this consent form as an Appendix. Side effects and risks of standard of care procedures are not described in this consent form.

This section describes the possible risks and/or discomforts we anticipate you could experience that are related to the study procedures.

**Unknown Risks**
There may be other side effects or risks that we cannot predict. Many side effects may go away shortly after the study medication or procedure is stopped. However, in some cases they can be serious, long-lasting, permanent, and/or fatal.

**Risks of posaconazole (Noxafil®)**

**Likely, Some May Be Serious (***Occurs in greater than 20% and up to 100 % of people***)**
- Diarrhea
- Pyrexia (fever)
- Nausea
- Hypokalemia (Low blood calcium levels)
- Rash
- Cough
- Nosebleed

**Less Likely, Some May Be Serious (***Occurs in >3% - 20 % of people)*
- Edema Peripheral (Swelling of lower legs or arms)
- Rash
- Thrombocytopenia (Low blood platelet count)
- Mucosal inflammation
- Headache
- Vomiting
- High blood pressure
- Abdominal pain
- Anemia (Low red blood cell count)
- Constipation
- Asthenia (Decreased muscle strength)
- Chills
- Hypomagnesemia (Low magnesium levels in blood)

**Rare AND Serious (***Occurs in 3% or less of people* ***and*** *may require hospitalization or may be irreversible, long-term, life-threatening or fatal***)**
- Clot in the lung
- Kidney Failure
- Liver Failure
- Pancreatitis
- Prolonged QT Interval on EKG (prolonged heart rhythm)
- Torsades de Pointes (Abnormal heart rhythm)

Reproductive and Lactation Risks
Taking part in this research study can affect an unborn baby. Therefore, you should not become pregnant or father a baby while on this study. If you or your partner is capable of becoming pregnant you will need to use birth control. Check with the researcher about approved birth control methods to use while participating in this study.

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Women should not breastfeed a baby while on this study.

Unknown Risks to the Developing Embryo or Fetus (an unborn baby)
If you are pregnant, or become pregnant during participation in this research, the study drug might involve risks to an embryo or fetus, which are currently unknown. It is important that you contact the researcher immediately if you believe you might be pregnant.

Follow-up Visit for Discontinuing Participants
While you are free to discontinue your participation at any time, we encourage you to complete a Final Study Follow-up Visit. During this visit, we will conduct tests to collect safety data, and discuss any information that may be important to share with your treating physician.

## 4. ARE THERE BENEFITS IN TAKING PART IN THE STUDY?

You should not expect to benefit from taking part in this research study.

We hope the information learned from this research study will benefit other individuals with Crohn's disease in the future by helping us to learn the effects of posaconazole on Crohn's disease.

## 5. WILL I BE INFORMED OF RESEARCH RESULTS?

Some of the research tests done in this study follow standard clinical procedures and are performed in certified clinical labs. These test results may be shared with you and may be placed in your Cedars-Sinai medical record. Other research tests done in this study are for research purposes only and are performed in a research only lab where the results are not intended for clinical use. These research-only results will not be shared with you or included in your Cedars-Sinai medical record.

Unanticipated Incidental Findings
If, unexpectedly, we find that results of your research procedures could suggest important medical information and we determine there is something you or your doctors can do in response to this finding, we will contact you using the last contact information provided by you. If necessary, we may recommend additional clinical testing to confirm the research finding. The cost of any additional testing and any related treatment will be your responsibility.

## 6. WHY WOULD MY PARTICIPATION BE STOPPED?

Your participation in this study may be stopped at any time by the researcher or the sponsor without your consent for any reason, including:

- The study is stopped or suspended;
- Funding for the study is reduced, stopped or withdrawn;
- If it is in your best interest;
- You do not consent to continue in the study after being told of changes in the research that may affect you;
- You do not follow the study procedures.

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## 7. ARE THERE ANY OTHER OPTIONS?

Your participation is voluntary, so you have the right to decline to participate or to withdraw from this research study at any time without any penalty or loss of benefits to which you would be entitled outside of the study. Choosing not to participate will not affect the care you receive at Cedars-Sinai Health System.

If you decide not to take part in this study, you have other choices. For example:

- you may choose to be treated following the usual clinical approach (commonly-used therapy, surgery, or participation in other studies)
- you may choose to take part in a different study at CSMC or elsewhere, if one is available
- you could decide not to be treated.

The researcher will discuss these options and their risks and benefits with you.

## 8. WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We will do our best to make sure that the personal information collected as part of this study is kept private. However, we cannot guarantee total privacy. A copy of your research consent and authorization forms may be filed in your electronic medical record at CSMC. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other identifiable personal information will not be used. Organizations that may look at and/or copy your medical records for research oversight, quality assurance, and data analysis include accrediting agencies, government and regulatory groups (such as Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), etc.), safety monitors, companies that sponsor the study, and authorized representatives of the sponsor.

Attached to this consent form is an "Authorization Form" that outlines with whom your information may be shared for the purposes of this research and under what circumstances.

We might share your information and/or research samples collected in this study with other researchers at Cedars-Sinai, other academic institutions, or third-party commercial entities for future research without additional informed consent from you. Information that identifies you will be removed and will not be shared with other researchers or anyone outside of Cedars-Sinai.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

## 9. WHAT IF I BECOME ILL OR INJURED BECAUSE OF TAKING PART IN THIS STUDY?

Contact your study doctor at once if you feel that you are ill or have been injured because of taking part in this study. If it is a medical emergency, call 911 or go to an emergency room. Promptly notify your study doctor of your situation at the phone number listed on page 1 of this consent form.

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Who pays for my research related illness or injury?
Cedars-Sinai has no plans to pay for costs associated with the treatment of research-related injury or illness. We will make every effort to seek reimbursement from your health plan. However, you will be responsible for any deductibles and co-payments required under your health plan and for any claims ultimately denied by your health plan. Financial assistance may be available under Cedars-Sinai's Charity Care Policy and Procedure. If you feel that you have had a research-related injury and need financial assistance, please contact the IRB Office at 310-423-3783. You do not waive any of your legal rights by signing this form.

## 10. FINANCIAL CONSIDERATIONS

Costs of Participation

You and your insurance company will not be charged for your participation in this research study. The Sponsor will cover the cost of all items, drugs and services required by this study, including any procedures required by the study that may be standard of care.

Compensation for Participating

You will be paid $50.00 for each research study visit. The total amount you will receive if you complete the whole study is $700.00. We will also provide you with a prepaid parking pass. If you do not complete the entire research study, you will only be paid for those visits you do complete. You may be required to complete a W-9 Form in order to receive payment. The W-9 Form will be maintained by our accounting department at Cedars-Sinai. Although any amount of payment may be reportable (check with a tax professional if you have questions about your obligations), if total payment by Cedars-Sinai is $600 or more in a calendar year, a 1099 Form will be filed with the IRS in accordance with federal tax law.

If you are a Cedars-Sinai employee, you should provide your employee identification number to the research team so that your payment can be appropriately processed through Payroll. For your own protection and to comply with tax laws, your payment for participation will be reported to the IRS together with other compensation you receive from Cedars-Sinai.

Compensation will be managed by a private company to issue a debit card onto which your compensation for research participation will be loaded. The funds will generally be available within 1 business day after you complete each study visit. To be able to issue you a debit card, we will need to share your name, address, social security number, and date of birth with the private company contracted to issue and manage the debit card. All information is stored in a secure fashion and is deleted from the debit card system once the study has been completed and the funds on the card have been exhausted. The private company will not share your information with any other third parties.

Financial Interest in the Research

The PI and institution have no potential financial conflict of interest with respect to this study.

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## 11. WHAT IF I HAVE QUESTIONS OR PROBLEMS?

Please contact the investigator listed on the first page of this form for questions or concerns about the research.

If you have questions, problems, or concerns that you want to discuss with someone who is not associated with this study, or want to offer suggestions or feedback, please contact:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: (310) 423-3783
Email: ResearchConcerns@cshs.org

The Cedars-Sinai HRPP has been established to protect the rights and welfare of research participants. You may also contact the Cedars-Sinai HRPP if you want to offer input or obtain information regarding the study.

## 12. CONSENT PROVISIONS

If you sign this form below, it means that:

(1) You have taken the time to carefully read and understand the information presented in this informed consent form; you should discuss it with others, and if appropriate seek a second opinion to make an informed decision;
(2) The information concerning the research study and its involved procedures has been fully explained to you and your questions have been answered to your satisfaction;
(3) You have received and understand all of the information you desire regarding your participation in the research study;
(4) You have considered the potential risks, any anticipated benefits and alternatives (and their relative risks and benefits) of participation;
(5) You are voluntarily agreeing to participate in this research study;
(6) You understand that by consenting to participate in the research, you are not giving up any of your legal rights (other than the postponement of your access to certain health information as described in this informed consent form);
(7) You understand that you have the right to be informed of significant new findings related to this research study which may affect your willingness to continue participating in this study; and
(8) You have been provided with a copy of the "Experimental Subject's Bill of Rights", if applicable to this research study, and have been provided with an opportunity to ask questions regarding the Bill of Rights.

We will give you a copy of this signed and dated consent form and the Experimental Subject's Bill of Rights.

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# SIGNATURE PAGE

## Consent Form for Research

**SIGNATURE BY THE PARTICIPANT:** *I hereby agree to participate in the research study described to me during the informed consent process and described in this informed consent form.* ***You will be given a signed copy of this form.***

| Name of Participant (Print) | Signature | Date Signed |
|---|---|---|

**SIGNATURE BY THE INVESTIGATOR:** *I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.*

| Name of Investigator (Print) | Signature | Date Signed |
|---|---|---|

Subject Initial: _____ Date: _____

## APPENDIX: FLOWCHART OF PROCEDURES

**LEGEND**
**R** = Research item/procedure done only for research purposes and covered by the study

Subject Initial: _____ Date: _____

| Procedures | Screening Visit | Baseline Week 0 | Week 2 | Week 4 | Week 6 | Week 8 | Week 10 | Week 12 | Week 16 | Week 20 | Week 24 | Week 28 | Week 32 | Week 36 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Informed Consent | R | | | | | | | | | | | | | |
| Medical History | R | | | | | | | | | | | | | |
| Eligibility Assessment | R | R | | | | | | | | | | | | |
| Height + Weight | R | | | | | | | | | | | | | |
| Vital signs | R | R | R | R | R | R | R | R | R | R | R | R | R | R |
| Concomitant medications | R | R | R | R | R | R | R | R | R | R | R | R | R | R |
| Physical Exam | R | R | R | R | R | R | R | R | R | R | R | R | R | R |
| Daily Diary instructions | R | R | | | | | | | | | | | | |
| Blood draw for genetics[3] | R | | | | | | | | | | | | | |
| Serum Pregnancy test | R | | | | | | | | | | | | | |
| Urine Pregnancy test | | R | R | R | R | R | R | R | R[1] | R[1] | R[1] | R[1] | R[1] | |
| Pharmacokinetics labs | | | R | R | R | R | R | R | | | | | | |
| hs-CRP lab | | R | R | R | R | R | R | R | R | R | R | R | R | R |
| Safety Laboratory tests | R | R | R | R | R | R | R | R | R | R | R | R | R | R |

| Procedures | Screening Visit | Baseline Week 0 | Week 2 | Week 4 | Week 6 | Week 8 | Week 10 | Week 12 | Week 16 | Week 20 | Week 24 | Week 28 | Week 32 | Week 36 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Stool pathogen tests | R | | | | | | | | | | | | | |
| Stool calprotectin | | R | R | R | R | R | R | R | R | R | R | | | R |
| Stool for microbiome analysis | R | R | R | R | R | R | R | R | R | R | R | | | R |
| Whole blood for Transcriptomics | R | | | | | | | R | | | | | | R |
| EKG | R | | R | | | | | R | R[1] | R[1] | R[1] | R[1] | R[1] | |
| Chest x-ray | R | | | | | | | | | | | | | |
| Colonoscopy with biopsies/SES-CD score | R | | | | | | | R | | | | | | R |
| Study therapy dispensing | | R | R | R | R | R | R | R[2] | R[2] | R[2] | | | | |
| Study therapy accountability | | | R | R | R | R | R | R | R | R | R | | | |
| Adverse event assessment | | R | R | R | R | R | R | R | R | R | R | R | R | R |
| Bowel movement diary | R | R | R | R | R | R | R | R | R | R | R | R | R | R |
| CDAI | R | R | R | R | R | R | R | R | R | R | R | R | R | R |
| Questionnaires | | R | R | R | R | R | R | R | R | R | R | R | R | R |

[1]Only required for participants receiving Open-label drug
[2]Dispensing for patients participating in Open-Label
[3] Subjects who have not previously had their CARD9 risk allele testing performed or who are not in MIRIAD or Mayo Clinic's IBD Biobank

Subject Initial: _____ Date: _____

## APPENDIX: Detailed Description of Common Medical Procedures Performed for Research Purposes and Associated Risks

***The procedures listed below are often performed as part of routine care for a person with your condition. They are being repeated or performed more frequently as part of this research. However, the risks associated with each procedure should be comparable to what you would experience even if you were undergoing the procedure outside this research study.***

| Study Procedure | Related Risks |
|---|---|
| **Blood draw:** A needle is placed in the vein in your arm to draw blood. | Blood drawing may cause some pain and has a small risk of bleeding, bruising, or infection at the puncture site. There is also a small risk of fainting. |
| **Electrocardiogram (ECG):** abbreviated as EKG or ECG – is a test that measures the electrical activity of the heartbeat using electrodes (disposable adhesive discs placed on the skin). | There's no pain or risk associated with having an electrocardiogram. When the disposable adhesive discs are removed from your skin, there may be some minor skin discomfort or irritation. You may experience temporary discomfort (pulling on the skin/skin hair) during removal of the patches. This hair may be shaved for patch placement. |
| **Chest X-ray:** A chest x-ray uses radiation to takes pictures of the heart, lungs, blood vessels and the bones of the chest. | The total amount of radiation you will receive for a chest x-ray is approximately 10 millirem (mrem is a unit of radiation dose). This is equivalent to 2% of the total amount a radiation worker is allowed to receive from radiation usage each year (5,000 mrem). This use involves minimal risk and is necessary to obtain the research information desired. |
| **Colonoscopy:** A colonoscopy is a visual examination of the colon (with a colonoscope) that requires sedation. A colonoscopy is a test that allows your doctor to look at the inner lining of your large intestine (rectum and colon). It helps finds ulcer, colon polyps, tumors, and areas of inflammation or bleeding. Before this test, you will need to clean out your colon (colon prep). Colon prep takes 1 to 2 days, depending on which type of prep your doctor recommends. | You may experience adverse reaction to the sedative used during the exam; bleeding from the site where a tissue sample (biopsy) was taken or a polyp or other abnormal tissue was removed; or a tear in the colon or rectum wall (perforation) |

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|---|---|
| **Biopsy:** A biopsy is the removal of a sample of body tissue for examination under a microscope, by the doctor or scientist, to determine the state of health or disease in the tissue. The type of biopsy you will require is dependent upon the disease/condition for which you are being treated. | There are some risks associated with biopsies. A small amount of bleeding, pain and skin bruising may occur. There is a potential for injury to internal organs from this procedure. These risks will be discussed with you further by the physician doing the biopsy. A separate summary of the risks associated with the type of biopsy you will require is included as an appendix to this consent form. The appendix describes the biopsy procedure and its risks in more detail, specific to the type of biopsy you will have.<br><br>If you have a bleeding tendency, you need to disclose this to the investigator and his or her staff. If you are taking aspirin, you will be advised to temporarily discontinue it. Infection is also a risk. Any additional specific risks will be disclosed prior to any procedure. |
| **Anesthesia during Colonoscopy procedure:** You will be given a medication to reduce the feeling of pain and discomfort during the colonoscopy and biopsy procedures. | Risks associated with anesthesia include short-term memory, feeling drowsy, not being able to think clearly, decreased blood pressure and decreased respiratory activity, nausea, vomiting, abnormal heart rhythms, and severe allergic reaction that could cause death. |
| **Physical Exam:** Includes height, weight, vital signs (heart rate and blood pressure). | There are no physical risks associated with these procedures. |
| **Concomitant Medications:** You will be asked about your previous and current medications that you take. | There are no physical risks associated with these procedures. |
| **Medical History Review:** You will be asked about your medical and surgical history, including dates of CD diagnosis, extent of disease and CD related hospitalizations. | There are no physical risks associated with this procedure. |
| **Urine Collection:** You will be asked to provide a urine sample in a collection cup. | No risks associated with this procedure. |
| **Pregnancy Test:** If you are a woman who is able to become pregnant, blood and urine samples will also be used to do a pregnancy test. | If your test is positive, you will be told and at that point you should discuss options available with your primary physician. |
| **Questionnaires:** You will be asked to complete a diary and questionnaires. We will ask you questions to evaluate your quality of life. We think it should take about 5 minutes to complete the questionnaire. Questionnaires will ask you | The questionnaire will be labeled with a unique study number that will link your identity so that only the research team can recognize you. |

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| | |
|---|---|
| to respond to questions about your general well-being, bowel movements and abdominal pain. | |
| **Demographic Information:** You will be asked about your age, gender, race, and ethnicity. | There are no physical risks associated with these procedures. |